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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN ROBERT MOBERG, ALEX YANG, CHRISTOPHER B. BRODEUR, WILLIAM JOSEPH WHEALON, KEE LEE, PHYLLIS YUEN, and DARREN DOUD

> Appeal 2015-004671 Application 12/768,281¹ Technology Center 3700

Before CHARLES N. GREENHUT, ANNETTE R. REIMERS, and NATHAN A. ENGELS, *Administrative Patent Judges*.

ENGELS, Administrative Patent Judge.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134(a) from a final rejection of claims 1, 2, 5–8, 11–13, 16–20, and 23. Claims 3, 4, 9, 10, 14, 15, 22, 25–29, 31, 32, and 34–38 are withdrawn from consideration. Claims 21, 24, 30, and 33 are canceled. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

¹ Appellants identify Covidien LP as the real party in interest. App. Br. 1.

ILLUSTRATIVE CLAIM

Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. An atherectomy catheter, comprising:

a body having opposite proximal and distal ends and a longitudinal axis, the body defining a lumen extending longitudinally therein and an opening in communication with the lumen;

a rotatable shaft extending longitudinally within the body lumen and being rotatable relative to the body; and

a cutting element adjacent the body opening having opposite proximal and distal ends, a length extending between the proximal and distal ends, and an outer, major diameter, the cutting element being coupled to the rotatable shaft for rotating the cutting element relative to the body about a longitudinal axis of the cutting element, the cutting element having a cutting edge configured for cutting tissue as the cutting element rotates and an abrasive surface spaced apart from the cutting edge on at least a longitudinal portion of the outer, major diameter surface of the cutting element configured for abrading tissue as the cutting element rotates

wherein the cutting element has a working position in which the cutting edge and the abrasive surface of the cutting element are exposed through the opening in the body to engage tissue outside the body of the catheter.

THE REJECTION

Claims 1, 2, 5–8, 11–13, 16, 19, 20, and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Simpson (US 2005/0177068 A1; Aug. 11, 2005) and Yock (US 5,865,178; Feb. 2, 1999).

Claim 17 stands rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Simpson, Yock, and Duer (US 5,512,044; Apr. 30, 1996).

Claim 18 stands rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Simpson, Yock, and Zacca et al. (US Re. 36,764; July 4, 2000).

ANALYSIS

The Examiner finds Simpson teaches each element of claim 1 except that Simpson does not disclose an abrasive surface spaced apart from the cutting edge on at least a longitudinal portion of the outer major diameter surface of the cutting element. Final Act. 3. The Examiner finds Yock teaches a cutting element having a rotatable cutting edge and an abrasive surface spaced apart from the cutting edge, as claimed, and concludes that it would have been obvious to a person of ordinary skill to place an external abrasive surface, as taught by Yock, on the cutting element of Simpson. Final Act. 3–4.

According to Appellants, "the dispositive issue on appeal is whether one skilled in the art would have modified the cutting element of Simpson . . . to include the element of 'an abrasive surface spaced apart from the cutting edge on at least a longitudinal portion of the outer, major diameter surface of the cutting element' in view of the teachings of Yock." Reply Br. 1; accord App. Br. 2–8. Specifically, Appellants argue the longitudinal portion of the outer, major diameter surface of the cutting element of Simpson is not designed to engage a patient's tissue and a person of ordinary skill would therefore not have applied an abrasive surface to the cutting element as claimed. App. Br. 4–6. Appellants also argue the abrasive surface disclosed in Yock "can be coextensive or contiguous with (e.g., abrasive material can be applied to) the forward cutting edge, whereby the

abrasive surface would <u>not</u> be spaced apart from the cutting edge or on a longitudinal portion of the outer, major diameter surface of the cutter." App. Br. 6–7; *see also* Reply Br. 9 (arguing a person of ordinary skill would not have understood Yock to teach placing an abrasive surface on the outer, major diameter surface of the cutter). Further, Appellants argue that even if Yock teaches or suggests an abrasive surface arranged as claimed, the Examiner "failed to provide articulated reasoning with some rational underpinning for modifying the cutting element in Simpson." App. Br. 4; *see also* Reply Br. 1–6 (addressing the semantics of the Examiner's Final Office Action, Advisory Action, and Answer).

We agree with Appellants that the Examiner has not adequately articulated why a person of ordinary skill would have modified the cutting element of Simpson to include an abrasive surface "spaced apart from the cutting edge," as claimed. Both Simpson and Yock describe in detail cutting elements for use with an atherectomy catheter, and both references mention that abrasion devices may also be used with a catheter for tissue removal. *See* Simpson ¶¶ 88 93; Yock col. 8, 11. 46–50.

Neither reference, though, discloses any structural details regarding abrasive devices or the arrangement of abrasive surfaces. Simpson describes "a tissue debulking assembly" that includes a rotatable cutter, and Simpson merely mentions that in "other embodiments, a tissue debulking assembly may include alternative or additional features for debulking a lumen. For example, the debulking assembly may include, but is not limited to, . . . an abrasion device" Simpson ¶ 88; *accord* Simpson ¶ 93 ("A debulking assembly, such as a cutter **28**, abrasive member, or the like, is disposed within a lumen **30** of the catheter body **22**."). Yock similarly lacks details,

stating only that "[a]s a modification of catheter 121, cutter 29 could be provided with an abrasive external surface, either in place of or in addition to the forward cutting edge. Such an abrasive surface would be useful to remove atheroma and plaque by contact abrasion." Yock col. 8, 11. 46–50.

Notably, the only evidence of record that provides structural details of a cutting element in combination with an abrasive surface is the Duer reference cited in the rejection of claim 17, but, unlike the abrasive surface of claim 1, Duer's abrasive surfaces are within the interior of a rigid housing and catheter body. Duer Figs. 2, 3, col. 3, ll. 5–10 (describing plaque "forced into the interior of rigid housing 20 and catheter body 30 to be further broken down and pulverized by an abrasive cylinder 65 and abrasive surface 66 within catheter body 30 (seen in FIGS. 2 and 3)"). Moreover, Duer states "cutter heads of conventional catheters often do not pulverize . . . plaque debris" (Duer col. 1, ll. 43–44).

We agree with the Examiner that the prior art teaches or suggests a cutting element in combination with an abrasive surface. Notably, though, the Examiner recognizes that a person of ordinary skill could have combined an abrasive surface with the cutting element of Simpson in a number of arrangements, "includ[ing], but . . . not limited to, placing the abrasive surface spaced apart from the cutting edge." Ans. 2–3 (emphasis added). In light of the specific arrangement recited in claim 1 and the lack of specifics or direction in the prior art, we find the Examiner has not adequately explained how or why a person of ordinary skill would have combined the prior art to arrive at cutting element with an abrasive surface arranged as claimed. See Unigene Labs., Inc. v. Apotex, Inc., 655 F.3d 1352, 1361 (Fed. Cir. 2011) (declining to find a claim obvious when the prior art does not

provide "indication of which parameters were critical" or "direction as to which of many possible choices is likely to be successful").

Accordingly, while we agree with the Examiner that the prior art teaches and suggests combining cutting elements and abrasive surfaces, we find the record lacks adequate evidence to support the Examiner's finding that the prior art teaches or suggests an abrasive surface "spaced apart from the cutting edge on at least a longitudinal portion of the outer, major diameter surface of the cutting element." We do not sustain the Examiner's rejection of claim 1, nor the rejections of claims 2, 5–8, 11–13, 16–20, and 23, each of which ultimately depends from claim 1.

DECISION

For the above reasons, we reverse the Examiner's rejection of claims 1, 2, 5–8, 11–13, 16–20, and 23.

REVERSED